FOOD MARKETING INSTITUTE

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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, Maryland 20852

Re: Proposed Labeling and Refrigeration Requirements for Shell Eggs (Docket Nos. 98N-1230, 96P-0418, and 97P-0197)

Dear Sir or Madam:

The Food Marketing Institute (FMI) is pleased to provide the following comments on the Food and Drug Administration's (FDA's) proposed rule to enhance the safety of shell eggs. 64 Fed. Reg. 36492 (July 6, 1999). The Agency has specifically proposed to require shell eggs that are held by retail establishments to be stored and displayed under refrigeration at a temperature of 45°F or less. In addition, FDA would require the use of a specific label intended to improve consumers' food safety habits with respect to shell eggs.

FMI supports FDA's goal of improving food safety for shell eggs and all food products. In this regard, we agree that shell eggs should be stored at 45°F ambient air temperature in retail establishments. However, slight variances in ambient air temperature should not render the eggs adulterated within the meaning of the Federal Food, Drug, and Cosmetic Act (the FD&C Act). Moreover, although we support the use of safe handling instructions on shell eggs, the label proposed by FDA is too lengthy and will be difficult for consumers to understand. Accordingly, we recommend that the Agency adopt labeling that is more consistent with the brief messages and icons developed by the Partnership for Food Safety Education's FightBAC! program, which is a coalition of industries, consumer groups, and government agencies, of which FDA is an important member.

FMI is a non-profit association that conducts programs in research, education, industry relations and public affairs on behalf of its 1,500 members and their subsidiaries. Our membership includes food retailers and wholesalers, as well as their customers, in the United States and around the world. FMI's domestic member companies operate approximately 21,000 retail food stores with a combined annual sales volume of $220 billion, which accounts for more than half of all grocery sales in the United States. FMI's retail membership is composed of large multi-store chains, small regional firms, and independent supermarkets. Our international membership includes 200 members from 60 countries.

98N 1230

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A. FMI Supports Refrigeration of Eggs at 45°F, Provided Minor Variations in Ambient Air Temperature Do Not Result in Condemnation of Eggs

FDA proposes to require the prompt refrigeration of shell eggs held for retail distribution and the refrigerated storage and display of these eggs at an ambient temperature not greater than 45°F when the eggs are held at the retail establishment. Proposed § 115.50(b).

FMI agrees that storing shell eggs at an ambient air temperature of 45°F at retail will contribute to improved food safety. However, maintaining the exact ambient air temperature at retail presents some unique challenges based on the equipment and the temperature of the eggs themselves that are not presented by other foods.

Specifically, our members advise that, despite their best efforts to maintain the ambient air temperature surrounding eggs at 45°F, the temperature will fluctuate. For example, when the door to a walk-in cooler is opened, the temperature will rise as a result of the in-flux of warmer air. Egg display cases undergo regular defrost cycles to maintain the efficiency of the equipment; during those cycles, air temperature will rise. Re-stocking display cases may raise the ambient air temperature if the eggs themselves are warmer than 45°F.[1]

The Food Code recognizes the difficulties inherent in storing and cooling shell eggs. Specifically, Section 3-501.14 requires most potentially hazardous food to be cooled to 41°F within four hours of receipt. Shell eggs are explicitly excepted from the requirement and are allowed longer than four hours to cool to the temperature required under the Code, provided that they are placed in refrigerated equipment that is capable of maintaining the required food temperatures immediately after receipt. See Food Code § 3-501.14; Annex 3, "Public Health Reasons" at 39.

The addendum to the Food Code explains that a separate method for cooling shell eggs is allowed in food establishments because of the cumulative information that has been gathered about the specific dynamics of the particular pathogen of concern in intact shell eggs. Annex 3, "Public Health Reasons" at 39. The Code further recognizes that rapid cooling of eggs may result in cracks and/or checks because of temperature gradients and that those imperfections may themselves promote migration of microorganisms through the shell. Id. As USDA requires shell eggs to be transported and distributed under refrigeration at an ambient temperature not to exceed 45°F, the Food Code recommends that food establishment operators maximize the circulation of cooled air in

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[1] In contrast, it is relatively simple to maintain a consistent 45°F ambient temperature in a refrigerator truck, which is only opened at the beginning and the end of transportation, and does not constantly receive supplies of new warm eggs.

refrigeration units to minimize the amount of time that eggs are stored at temperature that might allow the growth of *Salmonella* spp. Id.

FDA states that the purpose for the proposed ambient air temperature requirement is to help maintain the natural defenses of the egg and to limit the growth and reproduction of Salmonella enteretidis (SE). 64 Fed. Reg. at 36499. Thus, the purpose of the rule is general in nature, i.e., to lower and maintain the temperature of the eggs, rather than to ensure that a particular temperature is achieved within a specified time.

In determining the appropriate temperature at which the eggs should be held, the Agency notes that SE multiplies at temperatures of 50°F and above; multiplication of SE is inhibited at lower temperatures, such as 46°F and below. 64 Fed. Reg. at 36499. FDA further states that ambient temperatures do not correlate to the internal temperature of the eggs. 64 Fed. Reg. at 36494. Ambient air temperature was chosen by the Agency as the means to control the internal temperature of the eggs because it would be impracticable for either inspectors or retailers to monitor the actual internal temperature of the eggs. 64 Fed. Reg. at 36499.

FDA does not assert in the preamble that minor variations in ambient air temperature will result in significant increases in bacterial growth precisely because ambient air temperature is not necessarily an indicator of internal egg temperature. Since the safety control provided by temperature is inherently linked to time, a slight elevation in ambient temperature for a short period of time will not necessarily result in a higher internal egg temperature or any decrease in the safety of the eggs themselves. In justifying 45°F ambient air temperature, FDA acknowledges that a "lower temperature than 45°F would have a negligible effect on SE risk" because eggs cool down only slightly faster at lower temperatures. 64 Fed. Reg. at

Slight elevations in ambient air temperature are unavoidable during defrost cycles or when display cases are re-stocked with eggs. FDA states that "the internal temperature of the egg when the eggs are transported ranges between 50°F and 80°F." 64 Fed. Reg. at 36494. If eggs have an internal temperature of 50°F to 80°F when introduced into a display case at retail then an ambient air temperature at or near 45°F will continue to lower the temperature of the eggs, provided the equipment is capable of and programmed to maintain the temperature at 45°F. The retailer is doing everything possible to meet the requirements of the regulation and, in fact, is continuing to decrease the internal temperature of the eggs because the refrigeration element will continue to lower the ambient air temperature, which will, in turn, reduce the internal temperature of the eggs.

Our concern, then, lies with the Agency's tentative, but far-reaching, conclusion that storage of shell eggs at any temperature greater than 45°F will render the shell eggs adulterated under Section 402(a)(4) of the FD&C Act, regardless of the degree of temperature variation or the length of time of the fluctuation. Adulteration would mean that the eggs would be subject to condemnation under the FD&C Act, despite the fact that

the eggs themselves might be perfectly safe. Given the practical difficulties inherent in maintaining a 45°F ambient air temperature – difficulties which are recognized in the Food Code – and the absence of any evidence to indicate that minor fluctuations will affect food safety, eggs held above 45°F should not be considered to be adulterated under the FD&C Act simply on the basis of minor temperature fluctuations. Indeed, given the statutory authority provided by the Public Health Services (PHS Act), FDA need not reach the issue of the status of eggs held at temperatures slightly above 45°F under the FD&C Act in this rulemaking.

Specifically, as its statutory basis for the refrigeration requirement, FDA cites both the PHS Act and the FD&C Act. The PHS Act authorizes the Department of Health and Human Services – and, by extension, FDA – to make and enforce such regulations as are necessary to prevent the introduction, transmission, or spread of communicable diseases from one State into any other State. 64 Fed. Reg. 36498, citing 42 U.S.C. § 264(a). FDA provides compelling evidence to support the conclusion that disease outbreaks have been associated with the shipment of SE-contaminated eggs from one State to another and also with eggs that are not shipped across State lines. Accordingly, the PHS Act itself provides a sufficient legal basis to promulgate a regulation regarding refrigeration of shell eggs in retail establishments. As such, the Agency need not rely on the adulteration provisions of the FD&C Act, nor does FDA need to conclude that failure to refrigerate eggs would constitute insanitary conditions that may render the product injurious to health under the FD&C Act.

In addition to modifying the statutory basis for the 45°F standard, the Agency should consider the following remedies as well, since the procedures proposed under the PHS Act may also result in destruction of shell eggs for minor fluctuations in ambient temperature. First, FDA might require that shell eggs be stored under refrigeration and identify 45°F ambient air temperature as a voluntary, rather than a mandatory, standard. Second, FDA might establish a level of temperature variation that would be tolerated before the eggs would be subject to regulatory action, e.g., 45°F +/- 5°F.

Third, FDA should prepare enforcement guidance for use by the federal or state inspectors who will enforce the regulation to advise them that minor variations should not be the grounds for aggressive enforcement action and that a reasonable approach to determining compliance is appropriate. In this regard, the Agency might consider the directive that was issued by the Food Safety and Inspection Service (FSIS) regarding the enforcement of refrigeration and labeling requirements for shell eggs packed for consumer use. Directive 8840.1 (June 18, 1999). FSIS advises its inspectors to use a reasonable approach in monitoring ambient air temperature and references significant and repeated variations as the basis for enforcement actions. Given the variables in air temperature monitoring, inspectors charged with enforcing the proposed regulation might be advised to consider whether any extenuating circumstances might have influenced the temperature in a display case and, if so, to re-check the case a reasonable amount of time later to determine if the equipment has returned the ambient air temperature to a desirable level.

B. FMI Encourages FDA To Revise the Proposed Label To Focus on Educating, Rather than Frightening, Consumers

FMI supports the use of food safety labeling that will inform consumers of ways that they may safely handle eggs to reduce their risk of foodborne illness. See 64 Fed. Reg. at 36502. However, we are concerned that the proposed label will scare consumers away from a healthy food, rather than encourage them to handle the food safely. Accordingly, and as explained more fully below, we recommend that FDA re-design the label with simple instructions and icons that more closely reflect the messages developed by the Partnership for Food Safety Education.

FDA proposes to require the label of shell eggs to bear the following statement:

> SAFE HANDLING INSTRUCTIONS: Eggs may contain harmful bacteria known to cause serious illness, especially in children, the elderly, and persons with weakened immune systems. For your protection: keep eggs refrigerated; cook eggs until yolks are firm; and cook foods containing eggs thoroughly.

Proposed § 101.17(h). The Agency states that the wording of the proposed label was developed based on its recent experience with juice labeling and on the results of focus group research.

Although experience with juice labeling may be helpful, the juice label differs from the egg safety label in one critical respect. The juice label is intended only to warn consumers about the possible consequences of drinking unpasteurized juice; consumers are not asked to adopt any specific food safety practices that are necessary to ensure the safety of the juice. In contrast, the egg label is intended to encourage consumers to handle eggs safely. In this regard, consumers have a critical food safety role to play in contributing to the safety of the product. Thus, the experience with the juice label should not be relied on too heavily in developing a safe handling message for eggs.

We agree that focus groups are helpful tools to obtain feedback on proposed food safety messages. However, in this case, FDA tested four very similar versions of the same label, rather than trying different types of labels to determine which would be most effective. See 64 Fed. Reg. at 36503. In effect, FDA conducted a taste test with four different varieties of apples, when the Agency might better have focused its efforts by testing an apple, a plum, a grapefruit, and a banana. Although a McIntosh apple might have been the preferred apple, if all of the fruits were tested, the Agency might have discovered that grapefruits were actually even better for the purpose than any single type of apple.

We are concerned that FDA's message will be difficult for consumers to understand because we suspect that it is above the fifth grade reading level. Moreover, the initial, frightening aspect of the message may well discourage consumers from eating

a low-cost source of protein. Even if they do purchase it, the lengthy hazard message at the beginning is likely to prevent consumers from absorbing the safety instructions that follow at the very end.

As FDA knows well, the messages and icons of the Partnership for Food Safety Education were the subject of substantial testing and focus groups. Simple iconic representations transcend literacy and language barriers. Eggs are a major source of protein for low income people, some of whom may have lower literacy skills and/or may not read English well. If labeling is going to be relied upon to educate people about the importance of food safety, it should be easily comprehended and remembered by as broad a cross-section of society as possible.

Too many different types of warnings will result in consumer confusion and apathy. At this point, different warnings are being used for meat and poultry, juice, oysters, as well as other food products. The food safety agencies should standardize the warnings rather than adopt a broader variety of different statements. The general public is not aware that jurisdiction for different food products is spread among separate governmental agencies. Simple statements, accompanied with icons, such as the following, would be more effective than the lengthy warning FDA has proposed:

- Refrigerate promptly
- Cook thoroughly
- Do not eat raw

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We hope you will consider our comments favorably. If we may be of assistance in any way, please do not hesitate to call on us.

Sincerely yours,

Jill Hollingsworth
Vice President, Food Safety

CROSS FILE SHEET

File Number: 98N-1230/C

See File Number: 97P-0197/C

96P-0418/C

HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

CROSS REFERENCE SHEET

Docket Number/Item Code:	98N-1230/C671
See Docket Number/Item Code:	97P-0197/C672 96P-0418/C671

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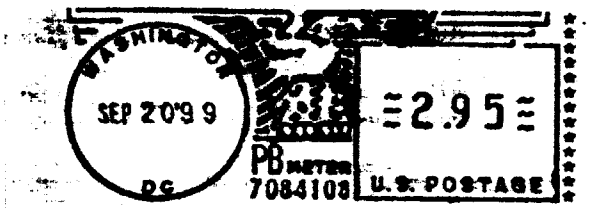

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